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Annual Report

Project Title: Virtual Reality and Cellular Phones as a Complementary Intervention for Veterans with PTSD and Substance Use Disorders

Award No.: W81XWH-08-2-0209

Principal Investigator: Mark Z. Rosenthal, Ph.D.

I. Introduction

In the present project, we are testing a novel adjunctive intervention designed to complement exposure-based therapies for combat veterans with posttraumatic stress disorder (PTSD) and co-morbid substance use disorders (SUDs). The novel intervention uses virtual reality as a cue exposure platform to extinguish cravings to drug-related cues, and cellular phones as an extinction reminder platform to transfer learning effects from exposure/extinction in the clinic to adaptive responses in high-risk contexts for drug use in everyday life. It is hypothesized that: (a) the complementary intervention will be acceptable and feasible and (b) compared to participants receiving exposure therapy alone, those receiving exposure therapy plus the complementary intervention will have better treatment outcomes at post-treatment and follow-up, as evidenced by lower PTSD symptoms, less substance use, and greater retention in treatment.

II. Body

Year 4 Tasks Outlined in the Statement of Work

These tasks below were identified in the Statement of Work as active tasks for year 4 (out of a planned four year project). Unfortunately due to the delay in study start up including all necessary regulatory approvals, we have requested a No Cost Extension (NCE) for an additional year. This fourth year of the project has continued to be dedicated to recruitment and completion of treatment for all participants. Preliminary analyses have been conducted and will be finalized in the NCE.

Participant Recruitment

Participant recruitment began in February, 2010. Recruitment methods have included posting flyers at the Durham VAMC and at selected treatment and community centers in the Durham area, advertisements on the DUMC website and local free newspaper, and direct referrals from VA clinicians. Over the past year, we completed 125 screening phone calls, yielding 68 individuals eligible to be scheduled for a diagnostic assessment. The reasons for ineligibility were not being interested (21 individuals), not having current substance use (inclusion criteria; 11 individuals), not being able to participate in treatment because of a conflict (10 individuals), being diagnosed with a psychotic disorder or mania (exclusion criteria; 8 individuals), homelessness (2 individuals), not being a veteran (2 individuals), and other (3 individuals). Combined with prior recruiting, we have completed 362 screening phone calls, yielding 162 individuals who were eligible for participation and 49 who were randomized. With the addition of the 12 month NCE, the pace of recruitment so far is adequate for reaching the study's recruitment goals. Our recruitment has improved through refinement of advertisements

to better target likely eligible individuals and through increasing contacts with therapists who treat individuals who would likely be eligible for the study.

Diagnostic Evaluations

Of the 68 potential participants scheduled for diagnostic interviews over the past year, 45 participated in interview assessments, yielding 23 participants who were enrolled in the study and randomized. The primary reason for exclusion from the study was not meeting criteria for PTSD. In total, we have randomized 49 participants into the study; however, 11 participants did not appear for their first therapy appointment leaving 38 participants in our intent to treat (ITT) sample.

Symptom Severity Evaluations

Symptom severity measures have been completed along with the diagnostic evaluations, described above.

Urine Testing

During this year, we conducted urine sampling with enrolled study participants. Urine testing is conducted 3 times a week, as stated in the study protocol.

Treatment

Over the past year, treatment for enrolled study participants was carried out by trained study therapists. New study therapists were also trained to join the treatment team.

Data Management, Statistical Analyses, and Statistical Consultation

Data collection has continued on the project. Screening data, diagnostic and symptom severity data, urine data, and weekly therapy-related assessments have all been collected for individuals who have had contact with the project. All data is entered into statistical software within a few days of being collected. No participant names are connected to unique ID numbers across all documentation, save for a single password protected electronic file used to maintain contact information, as described in the protocol. Statistical consultation has continued between the biostatistician, Dr. Strong, and Dr. Rosenthal, to facilitate effective and accurate data collection.

We have examined preliminary results regarding recruitment, retention, feasibility, acceptability, and outcome for the project. Of those who have completed treatment, 11 of the 19 participants (58%) assigned to the VR+PE condition dropped out of treatment, while 10 / 19 (53 %) of participants in the PE (control) condition have dropped out, suggesting that the addition of VR to standard PE does not alter the treatment retention typically seen in PE. Reasons for dropout are presented in Table 1. Six participants in each condition have completed treatment thus far. The 5 (3 PE only & 2 VR+PE) remaining participants in the ITT sample are currently in treatment.

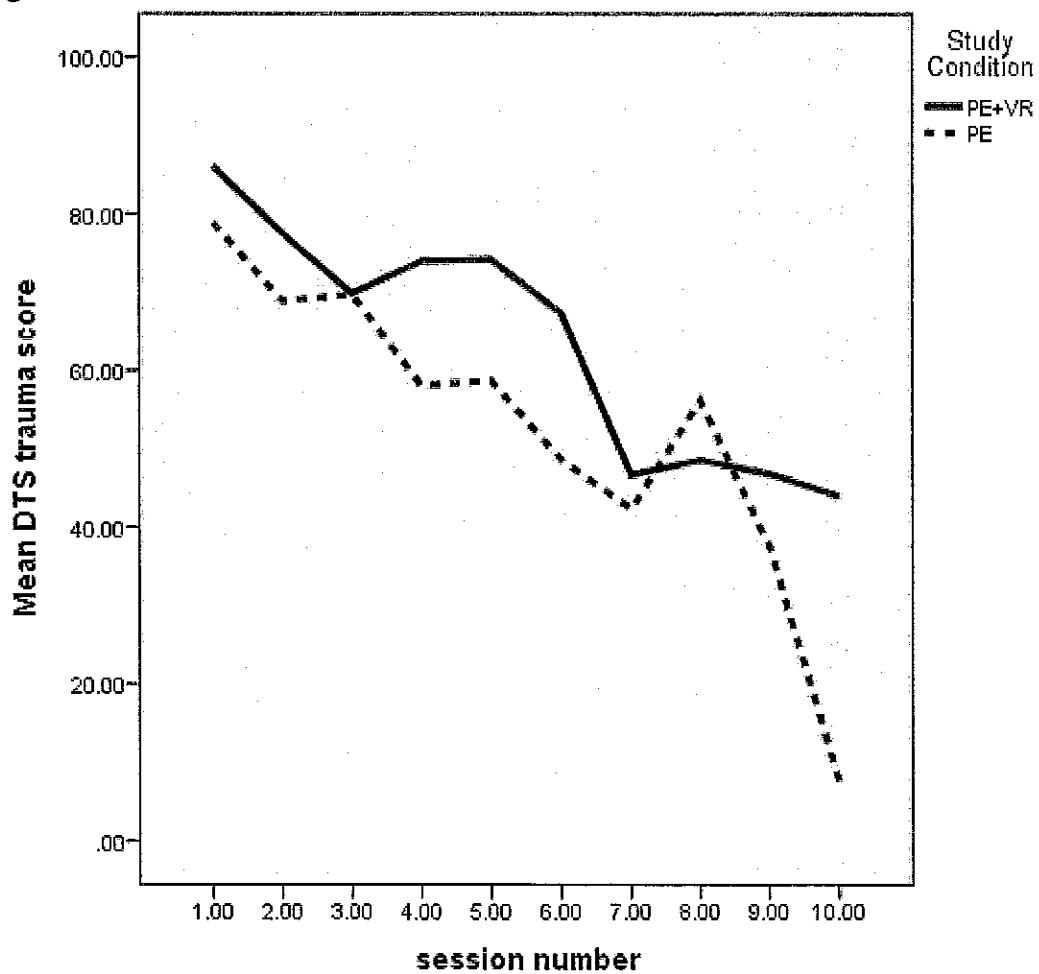
Table 1.

ID#	Condition	# Sessions	Reason for dropout
9005	PE	2	no reason given
9030	PE	4	did not want PE treatment after session 4
9037	PE	7	distance was too far to continue treatment
9043	PE	2	decided to start treatment at VA
9097	VR	3	Patient and therapist felt problems were too severe, started treatment at VA
9094	VR	2	did not want PE treatment after session 2
9110	PE	3	work schedule conflicted with treatment
9093	PE	6	Patient felt he was better after 6 weeks, wanted to look for a job
9103	PE	4	could not commit to PE treatment after session 4
9182	VR	2	no show after session 2
9209	PE	3	No show after session 3; no response to letters/phone calls
9223	VR	6	Participant couldn't get past the fear of talking about his past trauma and didn't want to experience PE at this time
9239	VR	1	PI decision-participant was dropped because his current substance use was too severe for PE
9254	VR	3	PI & Therapist decision-participant was not endorsing any trauma nor PTSD symptoms. Team and PI felt the study was not appropriate for participant
9265	VR	1	Participant moved out of the area due to a new job and stopped coming for appointments
9264	VR	2	No show after session 2
9273	PE	2	No show after session 2 & no response to calls or letter
9294	VR	3	Decided to discontinue treatment because of conflicts with work
9288	PE	1	Dropped after session 1 due to health; No response & no contact after he got out of the hospital.
9306	VR	2	PI Drop-Study team and parole officer all believed it was better for subject continue his current substance abuse treatment 3x week (which participant did not mention on screening day)
9304	VR	7	No show after session 7; no response to letters/phone calls

Throughout the study, 49 individuals qualified for the study (including those 11 who never initiated treatment). Among these individuals, 28 (57.1%) met criteria for current cigarette use, 24 (49%) met criteria for current alcohol abuse or dependence, 7 (14.3%) met criteria for cannabis abuse or dependence, 7 (14.3%) met criteria for cocaine abuse or dependence, and 1 (2.04%) met criteria for opioid abuse or dependence.

Preliminary longitudinal analyses with the Davidson Trauma Scale (DTS), a self report instrument which measures frequency and severity of PTSD symptoms indicate that both conditions (i.e., VR+PE and PE alone) have been successful at reducing PTSD symptoms significantly over time in the study ($F(1, 11.7) = 31.64, p <.001$). Figure 2 shows the change in DTS scores aggregated across participants in each treatment group. No significant change between conditions over time was found ($p > .05$)

Figure 2.



Mean differences in scores from pre-treatment to post-treatment for each interviewer-administered PTSD, substance abuse, or alcohol abuse outcome variable are presented in Table 2. As shown, participants have shown numerical improvement from pre- to post-treatment on all outcome measures except nicotine use.

Table 2.

Outcome Variable	Pretreatment	Posttreatment
	N=38	N=23
PTSD Symptoms, past month (CAPS)	94.26 (21.5)	59.32 (37.84)
Nicotine (Fagerstrom)	5.98(2.56)	7.33 (2.33)
Alcohol use (# times in past 30 days)	10.85 (10.06)	4.54 (7.48)
Heroin use (# times in past 30 days)	.53 (2.7)	.65 (2.92)
Cocaine use (# times in past 30 days)	2.03 (6.07)	.39 (1.47)
Cannabis use (# times in past 30 days)	3.97 (8.52)	1.74 (5.99)

Key Research Accomplishments

Research activities in year 4 have included:

- Training of study staff and therapists
- Continuation of recruitment and assessment
- Continuation of active treatment for participants in the study
- Continuation of data collection and data entry
- Continued regulatory review and approval of all study materials across the respective IRBs at DUMC, the Durham VAMC, and the USAMRRC.
- NCE request
- Preliminary Data Analyses

Reportable Outcomes

Because the study is still collecting data, there are no reportable outcomes from year 4.

Conclusions

There are no study conclusions from year 4. We anticipate study conclusions to be generated at or near the end of data collection, during year 5, the no cost extension

References

None



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